

REMARKS

Applicant requests reconsideration of the pending claims in this application in view of the following remarks.

Status of Claims

Claims 73, 75, 80, 81, 90, 93-96, 99, 101, 105-109, 117-121 are currently pending, with claims 73, 75, 80, 81, 90, 93, 95, 101, 105, 106 and 108 being independent. Claims 1-72, 74, 76-79, 82-89, 91-92, 97-98, 100, 102-104 and 110-116 have been cancelled, without prejudice to or disclaimer of the subject matter recited therein. Claim 101 has been amended to correct a typographical error.

Applicant thanks the Examiner for allowing claim 93-96, 106-109, 119 and 120 and for withdrawing all previously outstanding rejections.

Obviousness Rejections

Claims 73, 75, 80, 81, 90, 99, 101, 105, 117, 118 and 121 have been rejected under 35 USC 103(a) as being unpatentable over U.S. Patent No. 5,731,319 to Aberg et al. in view of U.S. Patent No. 6,372,802 to Hellberg et al. Applicant traverses these rejections and requests that they be withdrawn based on the comments provided below.

The cited references alone or in combination with each other do not disclose various features of the presently claimed invention. For example, the cited references alone or in combination with each other do not disclose, teach or suggest: (1) the total amount of desloratadine degradation products in the solid composition (e.g., claims 80, 81, 90, 101, 117); (2) a specific dissolution rate for desloratadine (e.g., claims 73, 80, 90, 105, 118, 121); or (3) a specified amount of antioxidant (e.g., claims 75, 81, 99). Claim 101 recites a solid composition that includes desloratadine and a desloratadine-protective amount of two pharmaceutically acceptable antioxidants (i.e., edetate disodium and citric acid), and specifies a total amount of desloratadine degradation. Applicant submits that each of these additional features renders Applicant's claimed invention unobvious over the cited documents.

The Office Action suggests that Applicant's claimed invention is unpatentable over the Aberg et al. patent in view of the Hellberg et al. patent because Applicant has not established the criticality of the claimed amounts of degradation products. Applicant submits that the FDA

disagrees with this suggestion as evidenced by the FDA Guidance for Industry, "Q3B(R2) Impurities in New Drug Products" (July 2006), a copy of which is attached, and 21 C.F.R. §§ 211.166 and 314.509(d)(1). This document states that it is critical to control the amount of degradation products in a composition intended for pharmaceutical administration to a human in order to ensure that the composition is both safe and effective. Controlling the amount of degradation products in a pharmaceutical composition is important for new drug approval and good manufacturing practices requirements set by the FDA. See the FDA Guidance for Industry, "Q3B(R2) Impurities in New Drug Products" (July 2006), and 21 C.F.R. §§ 211.166 and 314.509(d)(1). As suggested by Applicant's specification, the level of degradation products in the pharmaceutical composition is closely tied to the amount of pharmaceutically acceptable antioxidant present therein (e.g., see paras. [0031] to [0033]).

The FDA notes that it is important to achieve a particular dissolution profile for the composition so that appropriate bioavailability is obtained for the active ingredient when it is administered to a patient. (See 21 C.F.R. § 320.21 re bioavailability requirements in a new drug application.) As noted by the FDA (see FDA Guidance for Industry, "Dissolution Testing of Immediate Release Solid Oral Dosage Forms" (August 1997) at p. 1, copy attached):

Drug absorption from a solid dosage form after oral administration depends on the release of the drug substance from the drug product, the dissolution or solubilization of the drug under physiological conditions, and the permeability across the gastrointestinal tract. Because of the critical nature of the first two of these steps, in vitro dissolution may be relevant to the prediction of in vivo performance.

Given the complexities and many variables of developing stable pharmaceutical formulations that are both safe and effective, Applicant submits that Applicant's claimed invention is patentable and was not obtained through routine or manipulative experimentation alone. In view of the above, Applicant respectfully submits that the rejected claims are patentable over the Aberg et al. and Hellberg et al. patents and, therefore, that the outstanding rejection under 35 U.S.C. § 103 should be withdrawn.

Moreover, Applicant submits that withdrawal of the rejections based on Hellberg et al. is appropriate. The Office Action alleges that Hellberg et al. teaches methods and compositions for treating allergic diseases such as allergic rhinitis or sinusitis comprising disulfide derivatives. The Office Action contends that active ingredients in Hellberg et al. include antihistamines, such

as desloratadine and that edetate disodium is disclosed as a suitable chelating agent or stabilizer. The Office Action admits that Aberg et al. does not teach edetate disodium. The Office Action states that it would have been obvious to one of ordinary skill in the art to incorporate conventional chelating agents or stabilizing agents, such as edetate disodium as taught by Hellberg et al. within the formulations of Aberg et al. Applicant respectfully disagrees with this conclusion.

Applicant submits that Hellberg et al. distinguishes between antihistamines and mast cell stabilizers as two different types of drugs currently used topically to treat allergic diseases (e.g., see column 3, lines 24-30). Hellberg et al. suggests that excipients such as edetate disodium may be a chelating agent or stabilizer for a mast cell stabilizer such as a disulfide derivative, not for an antihistamine such as desloratadine (e.g., see column 3, lines 1-23). Applicant submits that there is no disclosure, teaching or suggestion that excipients useful for mast cell stabilizer disulfide derivatives would be useful for an antihistamine, such as desloratadine.

Further, Applicant submits that Hellberg et al. discloses that edetate disodium is an ophthalmically acceptable excipient. Ophthalmically acceptable excipients are directed to liquid compositions. Applicant's claims are directed to solid compositions. Applicant submits that liquids and solids are non-analogous. There is no disclosure or teaching in the cited references that listed excipients in Hellberg et al. are or would be an acceptable excipient in a solid dosage form as in the Applicant's claims.

Applicant submits that the Office Action picks and chooses parts of Hellberg et al. and Aberg et al. to support the improper conclusions that forms the basis of the rejections. It is impermissible within the framework of 35 USC § 103 to pick and choose from any one reference only so much of it as will support a given position to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one skilled in the art. *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc.*, 796 F2d 443, 230 USPQ 416 (Fed Cir 1986).

Accordingly, Applicant submits that withdrawal of the rejections based on cited references is appropriate and respectfully requests reconsideration.

Finality of Office Action

Applicant disagrees with the characterization of the Office Action dated December 13, 2007 as a final Office Action. As noted in MPEP ¶ 706.07(a),

second or any subsequent actions on the merits shall be final, except where the examiner introduces a new ground of rejection that is neither necessitated by applicant's amendment of the claims, nor based on information submitted in an information disclosure statement filed during the period set forth in the 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p).

In the Amendment in Response to Non-Final Office Action filed on September 27, 2007, Applicant canceled certain claims and rewrote each of claims 73, 75, 80, 81, 90, 101 and 105 in independent form containing all of the limitations of the base claim from which it previously depended. Moreover, claims 99, 117 and 118 were amended so as not to depend from non-cancelled claims. Claim 121 was added but was of the same form as claim 99. A terminal disclaimer was filed to overcome the double patenting rejections. No additional subject matter was introduced into the claims. Applicant respectfully submits that all of the rejections were addressed and overcome.

The Office Action dated December 13, 2007 agreed that the Applicant's Response of September 27, 2007 did overcome all of the outstanding rejections as it removed all prior rejections. A further rejection was made based on patents already of record and, indeed, previously applied in the Office Action dated August 2, 2007 (i.e., U.S. Patent Nos. 6,372,802 and 5,731,319). Applicants respectfully submit that this rejection was not necessitated by Applicant's amendment of the claims nor based on information submitted in an information disclosure statement filed during the period set forth in 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p).

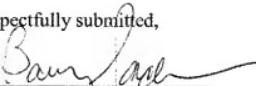
Applicants respectfully submit that the Office Action dated December 13, 2007 was not properly termed a final Office Action. Nonetheless, in the interest of expediting prosecution of this application, Applicant submits this Amendment and Response together with a Request for Continued Examination.

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In view of the above, Applicant submits that the remaining rejected claims are in condition for allowance in addition to those already identified in the Office Action as being allowed. Applicant further requests reconsideration and withdrawal of the outstanding rejection, as well as rapid passage of this application to issue. The Examiner is encouraged to contact Applicant's undersigned representative should there be any remaining issues precluding allowance of this application.

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